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Donini et al.(10) **Pub. No.: US 2016/0229890 A1**(43) **Pub. Date: Aug. 11, 2016**(54) **NOVEL PEPTIDES AND ANALOGS FOR USE
IN THE TREATMENT OF ORAL MUCOSITIS****Publication Classification**(71) Applicant: **Soligenix, Inc.**, Princeton, NJ (US)(72) Inventors: **Oreola Donini**, Coquitlam (CA); **Annett Rozek**, Port Moody (CA); **Jackson Lee**, Richmond (CA); **John North**, Comox (CA); **Michael Abrams**, Custer, WA (US)(51) **Int. Cl.****C07K 7/06** (2006.01)**A61K 31/573** (2006.01)**A61K 45/06** (2006.01)**A61K 38/08** (2006.01)(52) **U.S. Cl.**CPC . **C07K 7/06** (2013.01); **A61K 38/08** (2013.01);**A61K 31/573** (2013.01); **A61K 45/06** (2013.01)

(57)

ABSTRACT

Preclinical data obtained in models of chemotherapy-induced mucositis, radiation-induced mucositis, neutropenic infection and colitis indicate oral mucositis is a promising indication for Innate Defense Regulator (IDR) peptides. Preclinical efficacy results obtained with IDRs in mouse and hamster models of mucositis indicate that dosing every third day should be able to cover the mucositis "window" with seven to fourteen doses, depending on the duration of chemotherapy or radiation exposure. IDRs have also shown efficacy in mouse models of chemotherapy-induced oral and gastrointestinal mucositis, consistent with the response of the innate immune response to chemotherapy and/or radiation damage. IDRs are also effective at reducing bacterial burden and improve survival in the presence or absence of antibiotic treatment in various murine infection models.

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